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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,298	06/12/2000	DIETER LUBDA	MERCK2047	2130

7590

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EXAMINER

CHANG, VICTOR S

ART UNIT	PAPER NUMBER
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1771

DATE MAILED: 04/04/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/446,298

Applicant(s)

LUBDA ET AL.

Examiner

Victor S Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 3,5-15 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4 and 16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Rejections not maintained are withdrawn.

Election/Restrictions

3. Applicant's election with traverse of Claims 1, 2 and 4 in Paper No. 11 and request for reconsideration are acknowledged. The traversal is on the ground(s) that "Claims 3 and claims 5-15 clearly have Unity of Invention with claims 1, 2 and 4 because they all are based on the encased monolithic sorbent as recited in claim 1" (Response, page 3, 3rd paragraph). This is not found persuasive. The Examiner notes that the term "special technical feature" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art (see section 2 of Paper No. 12). Although claims 3 and 5-15 are based upon the "encased monolithic sorbent" of claim 1, the Examiner respectfully reiterates that WO 94/19687 either anticipates or makes obvious the "encased monolithic sorbent" of claim 1. As such, the technical feature "encased monolithic sorbent" does not make a contribution over the prior art, and the Unity of Invention does not exist (see section 3 of Paper No. 12).

The requirement is still deemed proper and is therefore made FINAL.

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4. Newly submitted claim 17 is clearly directed to the same group of non-elected inventions, claims 3 and 5-15. As such, claim 17 is withdrawn from consideration. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Amendment

5. Claims 1, 2 and newly added claim 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/19687 either taken individually, or in view of FR 2654835A (Derwent Abstract).

WO 94/19687 teaches a chromatography pillar comprised of a ceramic molded body surrounded by an impermeable Teflon material (Page 7 and Fig. 1). The porous ceramic molded body of WO '687 reads on Applicants' encased monolithic sorbent comprising a porous ceramic molding.

For claims 1, 2 and 16, WO '687 lacks express teaching that the ceramic body is encased by an impermeable pressure-resistant plastic casing such as a PEEK tubing. However, the Examiner takes Official Notice that it is common knowledge that a PEEK tubing is suitable as an impermeable pressure-resistant plastic casing for a chromatography column. Alternatively, FR '835 is directed to a high pressure liquid phase chromatography column comprising a PEEK tubing, and FR' '835 teaches that the advantages of PEEK tubing include: 1) easy to trim to the desired length, 2) do not require internal coating, etc. (Abstract). As such, it would have been obvious to one skilled in the art to replace the Teflon sleeve of WO '687 with the PEEK tubing of FR

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'835, motivated by the desire to improve the chromatography column manufacturing method.

With regard to Dr. Lubda's Declaration, which attests that Teflon sleeves failed at significantly low pressures, the Examiner notes that the data provided in Dr. Lubda's Declaration does not show the thickness of the sleeves. As such, it fails to show the results as a valid comparative study. Further, it should be noted that while an effective Declaration having a valid comparative study would have overcome the rejection as set forth in section 5 of Paper No. 12, this prior rejection is now withdrawn as being inferior to the new grounds of rejection as set forth above.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/19687 as applied to claim 1 above, and further in view of Nakanishi et al. (US 5624875).

It is noted that Applicants have not amended claim 4, and the Declaration by Dr. Lubda is not effective to overcome the new grounds of rejection of claim 1 as set forth above. As such, the prior art rejection of record as set forth in section 7 of Paper No. 12 is still deemed to be valid.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S Chang whose telephone number is 703-605-4296. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H Morris can be reached on 703-308-2414. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

VSC
April 1, 2003

DANIEL ZIRKER
PRIMARY EXAMINER
GROUP 1000
1700

Daniel Zinker